

Appl. No. 10/646,793
Amendment dated: April 4, 2005
Reply to OA of: December 2, 2004

Amendments to the Specification:

On page 3, please replace the fourth full paragraph which bridges page 4 with the following amended paragraph.

To achieve the object, the processes for preparing ~~[[the]]~~ a composition for treating a human liver of the present invention are described below. Artemisiae Capillaris and Gardeniae Fructus are ground, mixed with pure water, and decocted. Then, a Rhei Rhizoma herb and alcohol ~~solution is~~ are added to said mixture for precipitation to form the first solid phase and the first liquid phase, further said both phases are separated, and said first liquid phase is concentrated to form a liquid concentrate. Again, alcohol is subsequently added to said concentrate for precipitation to form the second solid phase and second liquid phase, and said second solid phase is separated and dried.

On page 5, please replace the first and second full paragraphs which bridge page 6 with the following amended paragraphs.

The present invention relates to a composition for treating hepatitis and a preparing method of the same, the processes are as follows: first, Artemisiae Capillaris and Gardeniae Fructus are ground to a powder, mixed with pure water, decocted, and then cooled to form a water extract. Wherein, said decocting step preferably is multiple boilings and stirrings, and said preferable cooling step is cooled at 10 to 80°C. Preferably, said Artemisiae Capillaris is selected from the group consisting of Artemisiae Capillaris, Herba Artemisiae Annuae, Artemisiae Scopariae Herba and the herbs of the same genus. On the other hand, said Gardeniae Fructus is preferably selected from the group consisting of Gardenia Jasminoides, Gardenia Radicans and the herbs of the same genus. Then, the Rhei Rhizoma herb and alcohol ~~solution is~~ are added to said mixture, said preferable extracting temperature is 10 to 80°C. Said Rhei

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Rhizoma is preferably selected from the group consisting of Rheum Officinale, Rhubarb Shui-Ken and the herbs of the same genus. At this time, the Schizandrae Fructus herb and alcohol ~~solution~~ is are optionally added. Wherein, said weight ratio of Artemisiae Capillaris to Gardeniae Fructus to Rhei Rhizoma is not limited, and preferably is 4-8 to 3-6 to 0.5-1.5, and more preferably is 4 to 3 to 1, 4 to 3 to 2, 4 to 6 to 1, or 8 to 3 to 2.

A first solid phase and a first liquid phase are formed after ~~mixing~~ extracting, and said two phases are then separated. Further, said first liquid phase is concentrated to form a liquid concentrate; preferably, said liquid concentrate is a concentrate containing 1 to 30 wt% solid. Then, alcohol is added to said concentrate for precipitation to form a second solid phase and a second liquid phase. Preferably, a final concentration of the added alcohol is greater than 30wt%. This step provides a first way and a second way in respect to conditions of the patient to be treated. The first way is adding alcohol until its final concentration is 71 to 90wt% to form a second solid phase and a second liquid phase. The second solid phase is dried, and packaged.

On page 6, please replace the Embodiment 1 in its entirety which bridges page 7 with the following amended Embodiment 1.

Embodiment 1

1. 8 kg of Artemisiae Capillaris, 6 kg of ground Gardenia Jasminoides and 144 kg of pure water are added together into a 250 ml decocting trough, then mixed and soaked for 13 h.
2. Said mixture is extracted at 80°C for 1 h, and cooled to 35°C for further use.
3. 2 kg of ground Rheum Officinale and 48 kg of 95% ethanol are added into the above-mentioned liquid decoction at 35°C for 1 h for extraction.
4. Said extraction of the liquid decoction is filtrated through a 200-mesh sieve and 168.89 kg of liquid extract is thus obtained, which contains 1.01wt% solid, measured by a moisture analyzer.

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5. Said liquid extract is concentrated under reduced pressure by vacuum concentrator to obtain 16.51 kg of liquid concentrate, containing 10.05wt% solid measured by moisture analyzer.
6. Said liquid concentrate is put into a precipitating tank and stirred by mechanical mixer. 15.58 kg of 95% ethanol is slowly added until final concentration of the mixed liquid concentrate is about 50%. Then, the mixer is stopped and incubated for 1h.
7. Said mixture is further filtrated by centrifugation using a centrifugal filtration, and the filtrate is then collected and dried by a lyophilizer to obtain 65.26 g of product, which is coded as ICH17. An animal study was performed with said product, and the results are shown as Tables 1, 3 and FIG. 6.

On page 7, please replace Embodiment 2 in its entirety which bridges page 8 with the following amended Embodiment 2.

Embodiment 2

1. 8 kg of Artemisiae Capillaris, 6 kg of ground Gardenia Jasminoides and 144 kg of pure water are added together into a 250 ml decocting trough and mixed for 13 h.
2. Said mixture is extracted at 80°C for 1 h, and cooled to 35°C for further use.
3. 2 kg of ground Rheum Officinalis and 48 kg of 95% ethanol are added to the above-mentioned liquid decoction at 35°C for 1 h. for extraction.
4. Said extraction of the liquid decoction is filtrated through a 200-mesh sieve to form 168.89 kg of liquid extract, containing 1.01wt% solid measured by a moisture analyzer.
5. Said liquid extract is concentrated under reduced pressure by a vacuum concentrator to obtain 16.51 kg of liquid concentrate, containing 10.05wt% solid measured by moisture analyzer.

6. Said liquid concentrate is put into a precipitating tank, and stirred by mechanical mixer. 62.3 kg of 95% ethanol is slowly added until the final concentration of the mixed liquid concentrate is about 80%. Then, the mixer is stopped and the concentrate is incubated for 1h.
7. Said mixture is further filtrated by centrifugation using a centrifugal filtrator, the supernatant is kept and then the filtrate is collected and dried by a lyophilizer to obtain 182.26 g of product, which is coded as ICH16. An animal study was performed with said product, and the results are shown as Tables 1, 3 and FIG. 5.
8. Said ~~discarded liquid filtrate~~ supernatant produced in step 7 is further concentrated to a certain concentration, and dried in the lyophilizer to obtain 1105.6 g of product coded as ICH19-1. ~~[[An]]~~ Another animal study was performed with said product, and the results are shown as Tables 1 and 3.

On page 8, please replace Embodiment 3 in its entirety which carries over to page 10 with the following amended Embodiment 3.

Embodiment 3

1. 8 kg of Artemisiae Capillaris, 6 kg of ground Gardenia Jasminoides and 144 kg of pure water are added together into a 250 ml decocting trough and mixed for 13 h.
2. Said mixture is extracted at 80°C for 1 h and cooled to 35°C for further use.
3. 2 kg of ground Rheum Officinale and 48 kg of 95% ethanol are added to the above-mentioned liquid decoction for extraction at 35°C for 1 h.
4. Said extraction of the liquid decoction is filtrated through a 200-mesh sieve to form 168.89 kg of first liquid extract, containing 1.01wt% solid measured by a moisture analyzer.

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5. Said first liquid extract is concentrated under a reduced pressure by a vacuum concentrator to obtain 16.51 kg of second liquid concentrate, containing 10.05wt% solid measured by a moisture analyzer.
6. Said second liquid concentrate is put into a precipitating tank and stirred by a mechanical mixer. 15.58 kg of 95% ethanol is slowly added until the final concentration mixed liquid concentrate is about 50%. Then, the mixer is stopped and the mixture is incubated for 1h.
7. Said mixture is further filtrated by centrifugation using a centrifugal filtrator, and then a third liquid filtrate is collected ~~put into~~ in a precipitating tank and stirred by a mechanical mixer. 46.73 kg of 95% ethanol is slowly added. Then, the mixer is stopped and the mixture is incubated for 1h.
8. Said mixture is further filtrated by centrifugation using a centrifugal filtrator, [[then]] the supernatant is kept, the filtrate is collected and dried by a lyophilizer to obtain 118.98 g product coded as ICH20. An animal study was performed with said product, and the results are shown as Tables 1, 3 and FIG. 7.
9. Said supernatant produced in step 8 ~~discarded liquid filtrate~~ is further concentrated to a certain concentration and dried in the lyophilizer to obtain 1102.7 g product coded as ICH19. [[An]] Another animal study was performed with said product, and the results are shown as Table 1 and 3.